

REMARKS

Applicant has reviewed the cited art and the Examiner's comments, and requests favorable reconsideration in view of the following remarks. In the Office Action mailed September 10, 2009, the Examiner rejected all pending claims 1-5, 7-8, 15-19 and 21-22 under 35 U.S.C. § 103(a) as being unpatentable over Reiss (USP 5,512,057) in view of Holsheimer (US 5,643,330).

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art; and
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. *Id.* at 17-18, 148 USPQ at 467. Such evidence, sometimes referred to as "secondary considerations," includes evidence of unexpected results. (MPEP § 2141(II)).

Before it is necessary to consider objective evidence, however, the Office must establish a *prima facie* case of obviousness. (The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. MPEP § 2142). To establish a *prima facie* case of obviousness, the Examiner must clearly articulate reasons with rational factual underpinnings to support the conclusion of obviousness. (MPEP §§ 2142 and 2143).

I. The Factual Underpinnings On Which The Examiner Relied In Rejecting The Claims Are Insufficient

All pending claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Reiss in view of Holsheimer. The Examiner asserted that Reiss describes all aspects of the claims except the use of implantable electrodes. The Examiner cited Holsheimer for a description of implanted electrodes. Specifically, the Examiner stated:

Holsheimer teaches that it is known to use electrodes implanted to the dura matter for use in interferential spinal cord stimulation as set forth in ABSTRACT for providing the predictable results of decreasing power consumption by placing the electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients.

(O.A., 9.10.09, p. 3).

Applicant respectfully disagrees. Contrary to the Examiner's assertion, neither the Abstract nor any portion of Holsheimer teaches the "use [of] electrodes implanted to the dura matter for use in interferential spinal cord stimulation" or "for providing the predictable results of decreasing power consumption."

The invention in Holsheimer is not concerned with interferential spinal cord stimulation (SCS), and thus Holsheimer does not describe an interferential SCS or any resulting beat frequency. In addition, the invention in Holsheimer is not concerned with "decreasing power consumption," as the Examiner alleged.

Rather, Holsheimer describes an apparatus that "provides the capability to change the depth and location of the stimulation by changing the amplitude or timing of one field with respect to another." Holsheimer further teaches that the "results are changed markedly by the use of multiple pulse generators connected to different electrodes positioned in a transverse plane with respect to the spinal cord." (Holsheimer, Col. 8, ln. 30-36). There is simply no discussion of "interferential spinal cord stimulation" or "decreasing power consumption" in Holsheimer.

The citation by the Examiner to the Abstract of Holsheimer or to Holsheimer generally for allegedly describing the use of electrodes implanted to the dura matter "for use in interferential spinal cord stimulation . . . for providing the predictable results of decreasing power consumption" is erroneous. Office personnel should make express fact-findings relating to the *Graham* factors, focusing primarily on the prior art teachings. (MPEP § 2144.08(II)(A)(5)). The fact-findings should specifically articulate what teachings or suggestions in the prior art would have motivated one of ordinary skill in the art to arrive at the claimed invention. *Id.* In this case, the factual underpinnings within Holsheimer on which the Examiner relied in rejecting the claims are erroneous. Therefore, the Office has not established a *prima facie* case of obviousness.

II. Applicant Submits A Declaration Under 37 CFR § 1.132 Of William Carroll As Evidence To Traverse The Rejection Of The Claims Under 35 U.S.C. § 103

Even if the Office had established a *prima facie* case of obviousness, the strong evidence of unexpected results here would overcome the *prima facie* case. Enclosed with this response is a Declaration under 37 CFR § 1.132 of William Carroll, attesting to the unexpected results achieved by the claimed invention.

"An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness." (MPEP § 716.02(c)). Below, Applicant compares the claimed invention with the cited Holsheimer and Reiss references, and demonstrates that the unexpected results are sufficient to rebut the present obviousness claim rejections.

A. Comparison of the Claimed Invention with Holsheimer

As explained in the Carroll Declaration, a study was performed by the Neuronano Lund Research Center University in Sweden to determine the stimulation effects created by an electrical stimulator that embodies the claimed invention. (*See* Exhibit B to the Declaration). The study compared the stimulation effects on the Gracile nucleus and the Pyramid tract (as an assay for pain relief) created by the claimed invention to such stimulation effects created by a conventional electrical stimulator as described, for example, in the Holsheimer reference.

The results of the study demonstrate that the activation thresholds in the Gracile nucleus and the Pyramid tract in the dorsal column are significantly lower when using 100 + 105 Hz interferential current stimulation than when using conventional 100 + 100 Hz stimulation. Furthermore, the same kind of results were obtained regardless of whether the conventional stimulation was performed in the parallel or crossed configuration (*See*, e.g., Declaration, para. 19-20). More specifically, the activation thresholds for the deep Pyramid tract were reduced by about 50% using the interferential current stimulation in either the parallel or crossed configuration. Moreover, the activation threshold for the Gracile nucleus was reduced by about 20% using interferential current stimulation in either the parallel or cross configuration. (*See*, e.g., Declaration, para. 19-20).

B. Comparison of the Claimed Invention with Reiss

Applying stimulation using conventional surface electrodes, as described in Reiss, does not enable deep penetration of the Pyramid tract. (*See*, e.g., Declaration, para. 23-24). Electricity follows a path of least resistance, and applying stimulation on the surface of the skin using surface electrodes does not allow for effective stimulation through the vertebrae. *Id.* Accordingly, it would be impractical to attempt to achieve the stimulation effects seen in the

results of the study in Exhibit A using surface stimulation because it would be highly likely that tissue damage and pain would be caused in the patient. *Id.*

C. The Declaration of William Carroll Demonstrates Unexpected Results

Using the interferential implantable electrode configuration of the present application enables for treatment of pain that cannot be effectively treated by either of the systems in Holsheimer or Reiss. Using the interferential implantable electrode configuration of the present application, interferential current recruits large numbers of dorsal column fibers and provides much greater levels of pain relief and benefit to intractable pain patients. (Specification, p. 2).

As explained above, it would be impractical to treat pain through stimulation of the Gracile nucleus and Pyramidal tract in the dorsal column using the system in Reiss. The voltage levels that would be required are at levels that would result in damage to tissue, causing further pain. (*See, e.g., Declaration, para. 23-24.*)

Similarly, the system in Holsheimer also fails to provide for effective treatment of pain through stimulation of the Gracile nucleus and Pyramidal tract in the dorsal column. Without using interferential current stimulation (e.g., such as by using conventional stimulation as in Holsheimer), the effect may be to spread stimulation through the cerebrospinal conductive fluid within the spinal cord, resulting in stimulation of the dorsal root ganglia, which causes chest and thoracic pain. (*See, e.g., Exhibit A to the Declaration, "Effectiveness of Spinal Cord Stimulation in the Management of Chronic Pain: Analysis of Technical Drawbacks and Solutions", Holsheimer, Jan, Neurosurgery: Volume 40(5), May 1997, pp 990-999.* In Holsheimer, most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column to the Pyramid tract to relieve pain. (Specification, p. 2). Thus, using the system in Holsheimer to provide for treatment of pain through stimulation of the Gracile nucleus

and Pyramidal tract in the dorsal column carries a significant risk of causing chest and thoracic pain as a side effect.

Furthermore, using the interferential implantable electrode configuration of the present application enables for stimulation of the Gracile nucleus and the Pyramid in the spinal cord using voltage levels that are sufficiently low to avoid the risks attendant in the systems of Holsheimer and Reiss. (See, e.g., Declaration, para. 24-25). As compared to Holsheimer, voltage levels are about half as much to activate the deep Pyramidal tract, and as compared to Reiss, voltage levels are orders of magnitude lower. Such results are a dramatic improvement over the results seen in the cited references. They are appropriately classified as a difference in kind, rather than one of degree, and are evidence of unexpected results sufficient to rebut a *prima facie* case of obviousness. (MPEP § 716.02).

Moreover, the results demonstrated by the study in Exhibit B to the Declaration are of a significant, practical advantage sufficient to rebut a *prima facie* case of obviousness. (MPEP § 716.02(a)(I)). Enabling for effective treatment of pain through stimulation of the Gracile nucleus and Pyramidal tract in the dorsal column without the risks present in the systems in Holsheimer and Reiss (the risks in Reiss are so high as to prevent a practical application of Reiss for such treatment) is significant for the population of patients with intractable pain.

III. Response to Rejection of Dependent Claim 8

With regard to dependent claim 8, the Examiner stated that Reiss in view of Holsheimer discloses the invention, but fails to explicitly teach the use of quadripolar electrodes. The Examiner further stated that "the Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss in view of Holsheimer with use of quadripolar electrodes since such a

modification would provide the predictable results of effective and efficient stimulation as well as facilitating controlling and directing the interferential field to the target site". (O.A., 9.10.09, p. 4).

"Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." (Memorandum from the Deputy Commissioner for Patent Examination Policy on the Procedures for Taking Official Notice, February 21, 2002). It would not have been well-known that interferential current stimulation may be performed using implantable quadripolar electrodes, as recited in the claims. Thus, Official Notice to this effect would be improper. If Applicant challenges a factual assertion as not properly based upon common knowledge, the Examiner must support the finding with adequate evidence. (MPEP § 2144.03(c)).

IV. Correction of Inventorship

Applicant thanks the Examiner for the indication that the inventorship of the application has been changed by deletion of Richard M. Terrell as an inventor. The Examiner indicated that the application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Applicant requests issuance of the corrected filing receipt at this time.

V. Conclusion

Applicant submits that all of the pending claim rejections have been overcome, and requests allowance of the claims at this time. Applicant requests that the Examiner call the undersigned at (312) 913-3331 with any questions or comments.

Respectfully submitted,
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